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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/932,128

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EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/932,128	Applicant(s) YGUERABIDE ET AL.	
	Examiner Nelson Yang	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-52,55,71-73,76,80,84,166-172,176-181,217 and 218 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-52,55,71-73,76,80,84,166-172,176-181,217 and 218 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2008 has been entered.

Response to Amendment

2. Applicant's amendment of claims 49-52, 55, 71-73, 76, 80, 84, 166-172, 176-181 is acknowledged and has been entered.
3. Applicant's addition of claims 217 and 218 is acknowledged and has been entered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 49-52, 55, 71-73, 76, 80, 84, 166-172, 176-179, 217, 218 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicoli et al. [US 4,647,544] in view of Rembaum et al. [US 4,929,400].

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With respect to claims 49, 166, Nicoli et al. teach colloidal gold particles which have been coated with a variety of macromolecules such as avidin, lectins, IgG in the size range of 20 to 500 nm (column 15, lines 25-35), which would therefore have the inherent feature of maximum wavelength absorption from 525 nm to about 635 nm, as evidenced by applicant's own specification (see para. 254, table 2). Although Nicoli et al. do not specify that the gold particles are further coated with a surface coat of gold, the surface of the colloidal gold particles taught by Nicoli et al. would also be gold, and therefore the particles would structurally be the same. These particles are found in homogenous immunoassays where analytes are detected using optical interference and specifically a Bragg scattering peak (column 5, lines 58-65). Nicoli et al. fail to teach that the coefficient of variation in size of the population of particles is less than 5%.

Rembaum et al., however, teach microspheres comprising materials such as silver, gold, and polyHEMA and having precise size range with diameters below 1000 Angstroms (column 8, lines 41-54, lines 55-69), varying no more than plus or minus 1% (column 3, lines 65-68), and having covalent functional groups for further reaction and attachment to other materials such as antibodies or proteins (column 3, lines 50-55). Rembaum et al. further teach that uniformly sized, small microsphere of the order of 100 Angstroms to 10 microns in diameter are preferred as carriers for biological substances such as antigens or antibodies, and that they provide monodispersity and result in less non-specific binding to the surface of cells or containers (column 2, lines 60-67).

Furthermore although neither Nicoli et al. or Rembaum et al. do not specify that the particles have a maximum absorption wavelengths of from about 525 nm to about 635 nm, this would be an inherent feature of the gold particles taught by Nicoli et al., as they have diameters

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that fall within the ranges disclosed by applicant to have a maximum absorption wavelengths of from about 525 nm to about 635 nm.

Therefore, it would have been obvious for the microspheres of Nicoli et al. to have precise size ranges varying no more than plus or minus 1%, as they are preferred as carriers for biological substances such as antigens or antibodies, as well as providing monodispersity and result in less non-specific binding to the surface of cells or containers. It would further have been obvious for the particles have to a maximum absorption wavelengths of from about 525 nm to about 635 nm through normal optimization procedures known in the art.

6. With respect to claims 50-52, Nicoli et al. teach colloidal gold particles coated with avidin and IgG (column 15, lines 25-35), which are both proteins and biopolymers. Rembaum et al. also teach microspheres created from polymers, proteins (column 3, lines 40-45). Although neither Nicoli et al. nor Rembaum et al. specifically recite that proteins do not significantly interact with light in the visible region of the spectrum, this property is inherent in proteins, and therefore would be anticipated by Nicoli et al. and Rembaum et al.

7. With respect to claim 55, the particles taught by Nicoli et al. are spherical (fig. 4C).

8. With respect to claims 71-73, 80, 84, Rembaum et al. teach microspheres created from polymers, proteins, waxes, starches, glasses, magnetic, and metals to impart various different properties to the particles (column 3, lines 40-50, column 4, lines 35-50), and also comprising materials such as silver, gold, and polyHEMA and having precise size range with diameters below 1000 Angstroms (column 8, lines 41-54, lines 55-69). Rembaum et al. further teach that the microspheres may comprise magnetic material (column 4, lines 1-10), in order to allow for magnetic separation of analytes from a mixture (column 7, lines 35-60).

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9. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the particles of Nicoli et al. to comprise magnetic material, so that analytes may be separated from a mixture magnetically, and to impart various different optical properties to the particles.

10. With respect to claim 76, Nicoli et al. teach colloidal gold particles which have been coated with a variety of macromolecules such as avidin, lectins, IgG in the size range of 20 to 500 nm (column 15, lines 25-35)

11. With respect to claim 167, Nicoli et al. teach different specific antibodies for binding to different antigens (column 23, lines 42-55).

12. With respect to claims 168-172, 176-179, 217, 218, Nicoli et al. teach colloidal gold particles which have been coated with a variety of macromolecules such as avidin, lectins, IgG in the size range of 20 to 500 nm (column 15, lines 25-35),

13. Claims 180, 181 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicoli et al. [US 4,647,544] in view of Rembaum et al. [US 4,929,400], as applied to claim 49 above, and further in view of Tarcha et al. [US 5,567,628].

With respect to claims 180, 181, Nicoli et al. discloses populations of gold particles and further comprising antibodies, but fails to teach that the antibodies are anti-biotin, anti-fluorescein or anti-digoxinin antibodies.

Tarcha et al., however teach the use of anti-biotin antibodies as a means for attaching biotinylated antibodies (column 23, lines 20-45), thus rendering the particles much more versatile.

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Therefore it would have been obvious in the invention of Nicoli et al. and Rembaum et al. to have particles comprising anti-biotin antibodies, as suggested by Tarcha et al., due to the greater versatility it provides the particles, allowing a greater variety of different antibodies to be attached.

Response to Arguments

14. Applicant's arguments with respect to claims 49-52, 55, 71-73, 76, 80, 84, 166-172, 176-161, 217, 218 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner, Art Unit 1641